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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA-HQ-OPPT-2012-0209; FRL-9907-36]

Final Enforceable Consent Agreement and Testing Consent Order for Octamethylcyclotetrasiloxane (D4); Export Notification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; enforceable consent agreement and testing consent order.

SUMMARY: Under the Toxic Substances Control Act (TSCA), EPA has issued a testing consent order (Order) that incorporates an enforceable consent agreement (ECA) with Dow Corning Corporation, Evonik Corporation, Momentive Performance Materials USA Inc., Shin-Etsu Silicones of America, Inc., and Wacker Chemical Corporation (the Companies). The Companies have agreed to certain environmental testing that will be used by EPA to characterize sources and pathways of release of octamethylcyclotetrasiloxane (D4) to the environment and resulting exposures of aquatic and sediment dwelling organisms to D4, contributing to the Agency's efforts to understand potential environmental effects of D4. This document revises the listing for D4 in the table of testing consent orders for substances and mixtures with Chemical Abstract Service (CAS) Registry Numbers. This document announces the ECA and the Order that incorporates the ECA for this testing, and summarizes the terms of the ECA. As a result of this action, exporters of D4, CAS No. 556-67-2, including persons who do not sign the ECA, are subject to TSCA export notification requirements.

DATES: The effective date of the ECA, the Order that incorporates the ECA, and this action is [*insert date of publication in the Federal Register*].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2012-0209, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For information on the ECA, contact:* Mark Seltzer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-2901; email address: seltzer.mark@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general. The requirements in the ECA and the Order that incorporates the ECA only apply to those companies that are specifically

named in the ECA. As of [*insert date of publication in the Federal Register*] any person who exports or intends to export any chemical that is the subject of the ECA and the Order that incorporates the ECA is subject to the export notification requirements of TSCA section 12(b) (see 40 CFR part 707, subpart D, and Unit IV.B.). Although other types of entities could also be affected, most chemical manufacturers are usually identified under North American Industrial Classification System (NAICS) code 325 (Chemical manufacturing).

II. Background

A. What is Octamethylcyclotetrasiloxane (D4)?

D4 is used as an intermediate for silicone copolymers and other chemicals. D4 is also used in industrial processing applications as a solvent (which becomes part of a product formulation or mixture), finishing agent, and an adhesive and sealant chemical (Ref. 1). It is also used for both consumer and commercial purposes in paints and coatings, and plastic and rubber products (Ref. 1) and has consumer uses in polishes, sanitation, soaps, detergents, adhesives, and sealants (Ref. 2).

B. Why Does EPA Need Environmental Effects Data on D4?

D4 persists in sediment and bioaccumulates in aquatic species. Data show D4 to be toxic to aquatic and sediment-dwelling species. EPA has concerns regarding the environmental effects of D4. Environmental testing will help develop a better understanding of the potential effects of this chemical in the environment.

III. ECA Development and Conclusion

A. How is EPA Going to Obtain Environmental Testing on D4?

EPA initiated steps and agreed to enter into this ECA with the Companies. On February 26, 2014, EPA received the ECA signed by the Companies, and on March 28, 2014, EPA signed the ECA and the Order that incorporates the ECA. The effective date of the ECA and the Order that incorporates the ECA is [*insert date of publication in the Federal Register*].

EPA uses ECAs to accomplish testing of chemicals for public health and environmental effects where a consensus exists concerning the need for and scope of testing (40 CFR 790.1(c)). The procedures for ECA negotiations and the factors for determining whether a consensus exists are described at 40 CFR 790.22.

B. What is the Subject of the ECA and Order Incorporating the ECA?

As specified in the ECA, the purpose of the testing program is to conduct environmental testing to help in characterizing sources and pathways of release of D4 to the environment and resulting exposures of aquatic and sediment dwelling organisms to D4.

The signatory companies shall submit a draft Study Plan and Quality Assurance Project Plan (QAPP) to carry out the environmental testing program set forth in Section VII. and Appendices 1-8 of the ECA. EPA will review of the signatory companies' draft submissions and, if consistent with Section IX.A. of the ECA, shall approve the submissions. The signatory companies shall conduct environmental testing in accordance with the Final Study Plan and Final QAPP approved by EPA. Following completion of environmental testing, the signatory companies shall submit a final report to EPA.

C. What Testing Does the ECA for D4 Require?

The ECA requires testing for the presence of D4 around specified wastewater treatment plants (WWTP) at the method detection limits specified in the test standards described in Appendices 4-8 of the ECA.

Environmental testing will be conducted at direct discharge sites WWTPs (Appendix 1 of the ECA). Direct discharge sites are D4 manufacturing and/or processing sites that discharge process wastewater into the environment after on-site wastewater treatment. The concentration of D4 in the WWTP effluent (Appendix 4 of the ECA), and surface water (Appendix 5 of the ECA), sediment (Appendix 7 of the ECA), and biota (benthic organisms and two species of fish as noted in Appendix 8 of the ECA) in the WWTP receiving stream will be measured.

Environmental testing will be conducted at WWTPs serving indirect discharge sites (Appendix 2 of the ECA). Indirect discharge sites are D4 processing sites (including product formulation sites) that discharge process wastewater to offsite WWTPs. The concentration of D4 in the WWTP influent (Appendix 4 of the ECA), effluent (Appendix 4 of the ECA), and biosolids (Appendix 6 of the ECA), along with surface water (Appendix 5 of the ECA), sediment (Appendix 7 of the ECA), and biota (benthic organisms and two species of fish as noted in Appendix 8 of the ECA) in the WWTP receiving stream will be measured.

Primarily non-industrial WWTPs receive less than 15% of wastewater from industrial facilities and, preferably, no wastewater from D4 manufacturing or processing (including product formulation) sites (Appendix 3 of the ECA). Environmental testing will be conducted at WWTPs serving primarily non-industrial wastewater treatment sites. The concentration of D4 in the WWTP influent (Appendix 4 of the ECA) and effluent

(Appendix 4 of the ECA), and biosolids (Appendix 6 of the ECA), along with surface water (Appendix 5 of the ECA), sediment (Appendix 7 of the ECA), and biota (benthic organisms and two species of fish as noted in Appendix 8 of the ECA) in the WWTP receiving stream will be measured.

Table 1.--Required Testing, Test Standards, Reporting Requirements: Phases of the Testing Program for D4

Event	Phase	Enforceable Consent Agreement (ECA) Section and Terms	Deadline (Days) ¹
1	Effective date	XXII. Date of Federal Register document publication	0
2	Submission of Study Plan to EPA	IX.A. No more than 120 days after effective date and at least 45 days prior to testing initiation	120
3	Submission of Quality Assurance Project Plan (QAPP) to EPA	IX.A. No more than 180 days after effective date and at least 45 days prior to testing initiation (EPA Requirements for Quality Assurance Project Plans (QA/R5)) (Ref. 3)	180
6	Study Plan/QAPP Approval	IX.A. Study plan/QAPP approval at same time, within 60 days of receipt of QAPP by EPA	240
7	Start of testing	IX.B. Testing start no more than 60 days after study plan/QAPP approval; specific tests to be conducted at each site type as described in Unit III.C.	300
10	End of testing	IX.B. Testing completed within 360 days of testing start	660
12	Environmental Monitoring Report	IX.D. Final report no later than 150 days following completion of testing	810

¹ Number of days, starting with the day following the completion of the previous ECA phase.

D. What are the Uses for the Test Data to be Developed Under the ECA?

The final report is intended to be released to the public, as described at Section IX.D. of the ECA. These data will be used to develop D4 environmental exposure and risk assessments. In addition, the data could be used by other Federal agencies (e.g., the

Agency for Toxic Substances and Disease Registry (ATSDR), the Consumer Product Safety Commission (CPSC), and the Food and Drug Administration (FDA)) in assessing chemical risks and in taking appropriate actions within their programs.

IV. Other Impacts of the ECA

A. What if EPA Should Require Additional Environmental Testing on D4?

If EPA decides in the future that it requires additional environmental testing data, the Agency has authority to re-open the testing consent order process according to 40 CFR 790.68.

B. How Does the Order Affect TSCA Export Notification?

As of the effective date of the ECA and the Order that incorporates the ECA under TSCA section 4 (i.e., the date of publication of this document in the **Federal Register**) any of the Companies, as well as any other person, who exports or intends to export any D4 that is the subject of this ECA and Order that incorporates the ECA, in any form, are subject to the export notification requirements of TSCA section 12(b).

Procedures related to export notification are described in 40 CFR part 707, subpart D.

EPA maintains lists of all chemical substances and mixtures with CAS numbers (40 CFR 799.5000) that are subject to testing consent orders. This document revises the listing for D4, CAS. No. 556-67-2, that is the subject of this ECA and Order that incorporates the ECA in the list at 40 CFR 799.5000.

Section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. EPA

has determined that there is good cause for adding this chemical to the list at 40 CFR 799.5000 without prior proposal and opportunity for comment because such notice and opportunity for comment is unnecessary since the export notification requirements are imposed by statute. Section 12(b) of TSCA requires any person who exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under TSCA section 4 to submit a notification of the export or intended export to EPA. TSCA section 12(b) operates regardless of whether this chemical is added to the list at 40 CFR 799.5000; the inclusion of this chemical in the list promotes awareness of that operation of statutory law. Therefore, EPA has determined that notice and an opportunity for comment on whether this chemical is added to the list at 40 CFR 799.5000 is unnecessary because the export notification requirements in TSCA section 12(b) would apply even if this chemical is not added to 40 CFR 799.5000.

C. What are the Economic Implications of the ECA?

Based on the economic analysis conducted for the ECA, the Agency expects the cost of the testing to be performed under this ECA to range from \$1,000,000 to \$1,200,000. The estimated total cost for industry to conduct the required testing under the ECA is \$1,200,000, which is the upper end of the estimated cost range. EPA anticipates that the costs for testing under this ECA will have a low potential for adverse economic impact on the regulated community because the costs for testing will be shared across five companies that are signatories to the ECA and the Order that incorporates the ECA.

Export regulations promulgated pursuant to TSCA section 12(b)--40 CFR part 707, subpart D--require only a one-time notification to each foreign country of export for each chemical for which data are required to be developed under TSCA section 4. EPA

prepared estimates of the cost and burden of the July 27, 1993, amendment to the rules implementing TSCA section 12(b) and included these in the Information Collection Request to support the rule most recently updated in 2012 (Ref. 4). EPA estimates that the average cost of preparing and submitting the TSCA section 12(b) notification for a submitter of any TSCA section 12(b) notification is \$79 when adjusted for inflation to 2012 dollars with an associated average burden of 1.3 hours (Ref. 5).

V. References

As indicated under **ADDRESSES**, a docket has been established for this final rule under docket ID number EPA-HQ-OPPT-2012-0209. The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Chemical Data Reporting Database. 2012.
2. EPA. Inventory Update Reporting Database. 2006.
3. EPA. EPA Requirements for Quality Assurance Project Plans (QA/R5).
4. EPA. Export Notification Requirement; Change to Reporting Requirements; Final Rule. **Federal Register** (58 FR 40238, July 27, 1993.)
5. EPA. Estimates of Burden and Costs for the Siloxanes Enforceable Consent Agreement. 2014.

6. EPA. EPA ICR No.: 0795.14 Information Collection Request for Notification of Chemical Exports -- TSCA Section 12(b) Supporting Statement for Request for OMB Review under the Paperwork Reduction Act, OMB Control Number 2070-0030. 2012.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866

This action announces an Order that incorporates an ECA between EPA and the Companies. Under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993), this action is not a “regulatory action” subject to review by the Office of Management and Budget (OMB).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid control number assigned by OMB. The OMB control numbers for the EPA's regulations in title 40 of the CFR are listed in 40 CFR part 9.

The information collection requirements related to the Order that incorporates the ECA have already been approved by OMB pursuant to PRA under OMB control number 2070-0033 (EPA ICR No. 1139.09). The one-time public burden for this collection of information is estimated to be approximately 200 hours per response (i.e., per company), or 1,000 hours total burden for the companies (Ref. 5). Under PRA, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it includes the time needed to review instructions; complete and review the collection of information; and transmit or otherwise disclose the information.

The information collection requirements related to export notification requirements under TSCA section 12(b), including those related to the ECA and the Order that incorporates the ECA, have already been approved by OMB pursuant to PRA under OMB control number 2070-0030 (EPA ICR No. 0795). The public reporting burden for this information collection is estimated to be 1.3 hours per response (Ref. 6).

C. Regulatory Flexibility Act (RFA)

Since the issuance of the ECA and the Order that incorporates the ECA, as well as the applicability of the export notification requirements of TSCA section 12(b) to chemicals addressed in the ECA and the Order that incorporates the ECA, do not require the issuance of a proposed rule, the requirements of RFA (5 U.S.C. 601 *et seq.*) do not apply.

D. Unfunded Mandates Reform Act (UMRA)

This action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of UMRA (2 U.S.C. 1501 *et seq.*). Therefore, this action is not subject to the requirements of UMRA.

E. Executive Order 13132 and 13175

This action is not expected to impact State or Tribal governments because these governments are not expected to export the chemicals covered by the ECA or the Order that incorporates the ECA. As such, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999). Nor will this action have Tribal

implications because it does not significantly or uniquely affect the communities of Indian Tribal governments, or involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply.

F. Executive Order 13045

Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), does not apply to this action because this action is not designated as an “economically significant” regulatory action as defined by Executive Order 12866 (see Unit VI.A.), nor does this action establish an environmental standard that is intended to have a disproportionate effect on children. To the contrary, this action will provide data and information that EPA and others can use to assess the risks of these chemicals, including potential risks to sensitive subpopulations.

G. Executive Order 13211

This action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

H. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of NTTAA (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical

standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The testing conducted under the ECA involves technical standards. The Agency conducted a search to identify potentially applicable voluntary consensus standards. No such standard was identified for environmental testing of D4 that is the subject of the ECA.

I. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, D4, Exports, Hazardous substances, Health and safety, Laboratories, Octamethylcyclotetrasiloxane, Reporting and recordkeeping requirements, Siloxane.

Dated: March 28, 2014.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 799--[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. In § 799.5000, revise the entry “CAS Number 556-67-2” to read as follows:

§ 799.5000 Testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers.

*	*	*	*	*
CAS Number	Substance or mixture name	Testing	FR Publication Date	
*	* *	* *	* *	
556-67-2	Octamethylcyclotetrasiloxane (D4)	Chemical fate	January 10, 1989	
		Environmental effects	January 10, 1989	
		Environmental testing	<i>[insert date of publication in the Federal Register]</i>	
*	* *	* *	* *	

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[FR Doc. 2014-07557 Filed 04/03/2014 at 8:45 am; Publication Date: 04/04/2014]